REMARKS

Obviousness-Type Double Patenting

Claims 25-27 and 33-58 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 12/037,556.

Terminal Disclaimer

Applicants are submitting a terminal disclaimer disclaiming the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the term of any patent granted on pending application USSN 12/037,556.

Reconsideration and withdrawal of the provisional non-statutory double patenting rejections in view of the terminal disclaimer is respectfully requested.

Rejection Under 35 U.S.C. § 112

Claims 26 and 27 are rejected under 35 U.S.C. § 112 because allegedly the Specification is not enabling for methods of prevention. Applicants respectfully disagree. The person skilled in the art would know that prevention is similar to treatment. Both involve the administration of a dose of the composition of the present invention. However, in order to advance prosecution Applicants have amended claim 26 by deleting the term "and/or prevention."

Claim 58 has been rejected because allegedly there is insufficient antecedent basis in claim 25 for the term "polyglycolized glyceride in claim 25. Claim 58 has been amended to depend from claim 40.

Reconsideration and withdrawal of these rejections under 35 U.S.C. § 112 is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

Claims 25-27 and 33-58 are rejected as being allegedly unpatentable over Patil (US 4,299,501) and Ranbaxy (WO 2002/017923).

Patil et al. relates to a process for preparing semisolid dispersion which comprises circulating oil and water phases from a single vessel through a system of mixers and homogenizers (Abstract). The final product is an emulsion (column 3, line 2). These emulsions are useful as creams, jellies, ointments and the like (column 1, line 4). A pharmaceutical material is an optional ingredient which may be either in the oil phase (column 2 line 68), in the aqueous phase (column 3 lines 7-8), or suspended in the emulsion (column 3 lines 1-2). It is important to note that the only use which Patil et al. suggest for the oil phase of their composition is to be mixed with a water phase and forced through a system of mixers and homogenizers until a suitable emulsion is formed.

Ranbaxy relates to a pharmaceutical composition for topical delivery of selective cyclooxygenase-2 enzyme inhibitor. The composition comprises selective cyclooxygenase-2 enzyme inhibitor, a gelling agent, and a solubilizing agent. Other optional components may be present (page 5, line 20 to page 6, line 2). In making the rejection under 35 U.S.C. § 103(a) the Examiner states that "it would have been obvious to one of ordinary skill in the art to substitute the carrier taught in Patil for the carrier of Ranbaxy for the predictable result of forming a stable composition for a stable composition for administration of COX-2 inhibitors, such as celecoxib."

Applicants respectfully disagree with this statement. As set forth above, the drug carrier in Patil et al. is the emulsion formed in the process claimed in Patil et al. If the carrier of Patil et al. is substituted for the carrier of Ranbaxy, the person skilled in the art would have a drug in a water containing emulsion and not Applicants' oil based composition. The person skilled in the art would not be motivated to use the oil phase of Patil et al. as a carrier because Patil et al. provide only one use for this oil phase, that is, being mixed with an aqueous phased and homogenized to form an emulsion. There is no

suggestion that the oil phase of Patil et al. has any other utility, and clearly no suggestion that the oil phase alone could be a carrier for a drug.

In order to combine elements from two references to render an invention obvious, there must be some motivation that would lead the person skilled in the art to combine the elements. In KSR v. Teleflex (500 U.S. ---- (2007)) the Supreme court states:

> ... it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. (Slip opinion p. 15)

Accordingly, KSR implies that there must be some reason that would have prompted a person of ordinary skill in the relevant field to take the oil phase of Patil et al., prior to emulsification, and substitute it for the carrier of Ranbaxy. In KSR the elements being combined all related to automobile brake pedals and thus, it was proper to combine them. In this case, the oil phase of Patil et al. is not a drug carrier, but rather the component of an emulsion. There is not motivation to take the oil phase of Patil et al. and use it as a carrier for the drugs of Ranbaxy.

The court in KSR warned against the dangers of hindsight (page 17 slip opinion). Applicants respectfully submit that it is only the teaching of Applicants' invention which shows that the oil component of Patil et al. could be used as the carrier for a drug. Applicants respectfully submit that it is only by hindsight that the Examiner can see how the composition of Patil et al. could be modified to achieve Applicants' invention.

Reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) is respectfully requested. Withdrawal of all rejections and timely allowance of the instant application is earnestly solicited.

Respectfully submitted,

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